

CLAIMS

1. A composition for rapid disintegrating tablets in oral cavity which comprises components (a) to (c) in such a manner that

(a) saccharides consisting of a combination of mannitol and one or more of other saccharide(s) selected from sorbitol, erythritol, maltitol, lactose, sucrose, glucose, fructose, maltose, trehalose, paratinit and paratinose are 40 to 90 parts by weight;

(b) an inorganic excipient is 1 to 30 part(s) by weight; and

(c) a disintegrating agent is 5 to 40 parts by weight

provided that total amount of components (a), (b) and (c) is 100 parts by weight.

2. The composition according to claim 1, wherein:

(a) saccharides are 50 to 80 parts by weight;

(b) the inorganic excipient is 2 to 15 parts by weight; and

(c) the disintegrating agent is 10 to 35 parts by weight.

3. The composition according to claim 1, wherein:

(a) saccharides are 65 to 80 parts by weight;

(b) the inorganic excipient is 3 to 10 parts by weight; and

(c) the disintegrating agent is 17 to 34 parts by weight.

4. The composition according to any one of claims 1 to 3, wherein mannitol and other saccharide(s) form complex particles and the inorganic excipient and the disintegrating agent are dispersed in the

complex particles.

5. The composition according to claim 4, wherein the complex particles form a solid dispersion.

6. The composition according to any one of claims 1 to 5, wherein other saccharide(s) depresses the melting point of mannitol.

7. The composition according to any one of claims 1 to 6, wherein an endothermic peak of the saccharides is shifted to a low temperature side by 0.5 to 10°C compared to an endothermic peak measured from mannitol only.

8. The composition according to any one of claims 1 to 7, wherein the ratio by weight of mannitol to other saccharide(s) is (98 to 67) : (2 to 33).

9. The composition according to any one of claims 1 to 7, wherein the ratio by weight of mannitol to other saccharide(s) is (96 to 81) : (4 to 19).

10. The composition according to any one of claims 1 to 9, wherein the inorganic excipient has an average pore diameter of 100 nm or less and is a pharmaceutically acceptable inorganic compound containing any of aluminum, magnesium and calcium.

11. The composition according to any one of claims 1 to 10, wherein the inorganic excipient is selected from magnesium aluminometasilicate, magnesium aluminosilicate, synthetic hydrotalcite, calcium silicate, calcium hydrogen phosphate, calcium carbonate, talc and dry aluminum oxide gel.

12. The composition according to any one of claims 1 to 11, wherein the disintegrating agent has an average particle diameter of 60 μm or less, and is selected from crospovidone, low-substituted hydroxypropyl cellulose, crystalline cellulose and croscarmellose sodium.

13. The composition according to claim 12, wherein one or more of disintegrating agent having an average particle diameter of 20 μm or less is contained.

14. The composition according to any one of claims 1 to 12, wherein the disintegrating agent is crospovidone having an average particle diameter of 20 μm or less and crystalline cellulose having an average particle diameter of 40 μm or less.

15. The composition according to any one of claims 1 to 14, which contains 5 to 13 parts by weight of crospovidone and 12 to 21 parts by weight of crystalline cellulose as the disintegrating agent.

16. The composition according to any one of claims 1 to 15, which is obtained by spray-drying an aqueous solution or an aqueous dispersion comprising the saccharides, the disintegrating agent and the inorganic excipient.

17. The composition according to claim 16, which is obtained by spray-drying the dispersion obtained by dissolving or dispersing, in advance, mannitol and other saccharide(s) in an aqueous medium and then homogeneously dispersing the disintegrating agent and the inorganic excipient.

18. The composition according to any one of claims 1 to 17, which further contains 0.01 to 100 parts by weight of a pharmacologically active ingredient and/or 0.01 to 1000 parts by weight of a component which does not deteriorate a disintegrating property based on 100 parts by weight of a total amount of the saccharides, the inorganic excipient and the disintegrating agent.

19. A rapid disintegrating tablet in oral cavity prepared by using the composition according to any one of claims 1 to 18, which comprises 0.01 to 100 parts by weight of a pharmacologically active ingredient and/or 0.01 to 1000 parts by weight of a component which does not deteriorate a disintegrating property based on 100 parts by weight of the composition.